

## **REMARKS/ARGUMENTS**

Claims 1-38 are currently pending. Claims 1-16 have been withdrawn from consideration. Claim 39 has been cancelled. Claims 17, 25 and 35 have been amended to recite the limitation of cancelled claim 39. No new matter has been added with this amendment.

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

### **35 U.S.C. §102 Rejections**

Claims 17-25 and 28-39 have been rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent 5,380,299 to Fearnot (the Fearnot patent). This rejection is respectfully traversed.

The Applicants have thoroughly considered the Examiner's remarks concerning the patentability of claims 17-25 and 28-39 over the Fearnot Patent. The Applicants have also thoroughly read the Fearnot Patent. In order for the Fearnot Patent to anticipate the invention as claimed in amended independent claims 17, 25 and 35, the Fearnot Patent must disclose, teach, or suggest each and every claimed element of the Applicants' invention, "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Referring to claims 17, 25 and 35, claims 17, 25 and 35 have been amended to recite the limitation of cancelled claim 39. Therefore, no new matter has been added with this amendment. Claims 17, 25 and 35 have been amended to recite a stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include at least one therapeutic agent and a cured first polymer and wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation.

The Fearnot Patent does not disclose, teach, or suggest, each of the limitations as recited in amended claims 17, 25 and 35. Specifically, the Fearnot Patent does not teach “wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation” as recited in amended claims 17, 25 and 35. The Fearnot Patent merely teaches a stent having a multi-layer coating where the coating is allowed to air dry between coats (see col. 4 lines 11-16). In rejecting the limitation of (cancelled) claim 39, now added to claims 17, 25 and 35, the Examiner states that the Fearnot Patent discloses “a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a first polymer, which is inherently cured by one of thermal activation, electrical activation, or ionizing irradiation” (see page 2 of the present Office Action).

As the Examiner is well aware, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).” Additionally, “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).” Furthermore, “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient’ (see MPEP 2112).

In the present case, the Examiner has provided neither a basis in fact and/or technical reasoning to reasonably support the determination of inherency nor extrinsic evidence to support a finding that the missing descriptive matter is necessarily present in the stent described in the reference. At most, the Examiner points to col. 2, ll. 10-26 (reproduced below) to provide evidence of all claim limitations recited in claims 17, 25 and 39.

10    The method of treating a medical device with a  
     thrombolytic agent comprises providing a base material  
     for the medical device along with the thrombolytic  
     agent. The base material is treated with the thrombo-  
     lytic agent to advantageously dissolve the thrombus on  
15    the surface of the medical device. The base material is  
     advantageously dipped into a solution of the thrombo-  
     lytic agent and then removed to allow the thrombolytic  
     agent to dry thereon. The steps of dipping and drying  
20    the base material and the thrombolytic agent is repeated  
     to form a desired concentration or quantity of thrombo-  
     lytic agent on the base material. The method further  
     includes providing a polymer or a biologically derived  
     material and mixing the thrombolytic agent with the  
25    polymer or biologically derived material and applying  
     the mixture to the base material.

The citation of this material does not satisfy the Examiner's burden of providing the rationale or evidence tending to show inherency as required by MPEP 2112. For this reason, the Applicants request that the Examiner withdraw the finality of the rejections of the pending claims and provide the requisite extrinsic evidence to reasonably support the determination that the limitation of curing a first polymer by one of thermal activation, electrical activation, or ionizing irradiation recited in amended claims 17, 25 and 35 is inherently present in the Fearnot patent teaching of allowing a coating to dry in room air.

Therefore, as each and every limitation of amended independent claims 17, 25 and 35 is not disclosed in the Fearnot Patent, claims 17, 25 and 35 cannot be anticipated by the Fearnot Patent.

Claims 18-24 depend from independent claim 17 and include all the elements and limitations of independent claim 17. Therefore, dependent claims 18-24 are allowable over the Fearnot Patent for at least the same reasons as set forth above with respect to independent claim 17.

Claims 28-34 depend from independent claim 25 and include all the elements and limitations of independent claim 25. Therefore, dependent claims 28-34 are allowable over the Fearnot Patent for at least the same reasons as set forth above with respect to independent claim 25.

Claims 36-38 depend from independent claim 35 and include all the elements and limitations of independent claim 35. Therefore, dependent claims 36-38 are allowable over the Fearnot Patent for at least the same reasons as set forth above with respect to independent claim 35.

For these reasons, the withdrawal of the rejection of claims 17-25 and 28-38 under 35 U.S.C. § 102(b) is respectfully requested.

35 U.S.C. §103 Rejections

Claims 26 and 27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fearnot '299 in view of Guruwaiya (US Patent 6,251,136).

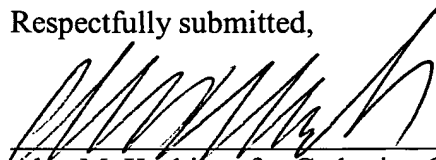
The Applicants traverse this rejection. As the Examiner is well aware, in order to make a *prima facie* case of obviousness under § 103(a), all of the *claimed* elements of the invention must be taught or suggested by the prior art (MPEP § 2143.03). As discussed above, the Fearnot patent does not teach or suggest a drug polymer layer having at least one therapeutic agent, a cross-linking agent and a cured first polymer as claimed in independent claim 25. The Guruwaiya patent does not cure this defect. Furthermore, the Fearnot patent in combination with the Guruwaiya patent does not teach or suggest a drug polymer layer having at least one therapeutic agent, a cross-linking agent and a cured first polymer as claimed in amended independent claim 25.

Claims 26 and 27 depend from independent claim 25 and include all of the elements and limitations of independent claim 25 and, thus, are allowable for at least the same reasons as those stated above for claim 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 26 and 27 under § 103(a).

**Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,



Alan M. Krubiner for Catherine C. Maresh  
Registration No. 26,289 for 35,268  
Attorney for Applicant

Medtronic Vascular, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403  
Facsimile No.: (707) 543-5420